K073573

AgaMatrix

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JAN 30 2008

510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: unknown

1. **Submitter's Name, Address, Telephone Number, Contact Person, and date the summary was prepared.**

Submitter's Name:	AgaMatrix, Inc. 10 Manor Parkway Salem, NH 03079
Contact Person:	Connie Hertel Director Quality & Regulatory Affairs
Telephone:	(603) 328-6051
Fax:	(603) 893-4191
Date the summary prepared:	December 6, 2007

2. **Device Name**

Trade/Propritary Name:	WaveSense™ KeyNote Codeless Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Monitoring System
Classification Name:	Glucose Test System (per 21 CFR 862.1345)
Class:	II
Panel:	Chemistry

3. **Modification Device**

The modification of the WaveSense Jazz™ Blood Glucose Monitoring System (Codeless) excludes two User Interface features: meal time tagging and positive feedback (smiley face). In addition, the meter's shell has been modified.

4. **Description of the Device:**

The AgaMatrix WaveSense™ KeyNote Codeless Blood Glucose Monitoring System includes a meter with batteries, compact carrying case, lancing device, lancets, control solution and owner's booklet. Test Strips are sold separately.

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It is intended for over-the counter home use by diabetics to monitor their blood glucose levels, or for use in a clinical setting by healthcare professionals. The system tests fresh capillary whole blood. The meter is a portable, battery-operated instrument.

5. Intended use of the device:

The WaveSense™ KeyNote Codeless Blood Glucose Monitoring System is intended to quantitatively measure blood glucose levels, also known as blood sugar, from fresh capillary whole blood samples taken from the fingertips, palm, or forearm. The WaveSense™ KeyNote Codeless Blood Glucose Monitoring System test strips are for in vitro diagnostic (outside of the body) use only. The WaveSense™ KeyNote Codeless Blood Glucose Monitoring System is not intended for use with neonates.

Testing:

The manufacturer of the WaveSense™ KeyNote Codeless Blood Glucose Monitoring System certifies that the device complies with the following:

ISO 15197:2003 *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 14971:2000 Medical devices – Application of risk management to Medical devices

IEC 61010-1 Medical electrical equipment – General requirements for safety

IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use – particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61000-4-3 Electromagnetic compatibility (EMC)

8. Conclusions

Based upon the testing and comparison to the predicate device, the WaveSense™ KeyNote Codeless Blood Glucose Monitoring System Blood Glucose Monitoring System has the same intended uses, with similar technological characteristics as the predicate device. The system performs as intended and raises no new safety or Effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 30 2008

AgaMatrix, Inc.
c/o Ms. Connie Hertel
Director Quality & Regulatory Affairs
10 Manor Parkway
Salem, NH 03079

Re: k073573
Trade Name: WaveSense™ Keynote Codeless Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: January 16, 2008
Received: January 18, 2008

Dear Ms. Hertel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k073573

Device Name: **AgaMatrix WaveSense™ KeyNote Codeless Blood Glucose Monitoring System**

Indication For Use:

AgaMatrix WaveSense™ KeyNote Codeless Blood Glucose Monitoring System:
AgaMatrix WaveSense KeyNote Codeless Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger stick, palm, and/or forearm. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___X___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073573